11-13-00 A

Please type a plus sign (+) inside this box [+]

UTILITY PATENT APPLICATION TRANSMITTAL

(only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	MCP-264
First Named Inventor or Application Identifier	Codispoti
Express Mail Label No.	EL190925968US

APPLICATION ELEMENTS

See MPEP Chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. ☒ Fee Transmittal Form *(attached hereto in duplicate)*
2. ☒ Specification [Total Pages 9]
(Preferred arrangement set forth below)
   - Descriptive Title of the Invention
   - Cross References to Related Applications
   - Statement Regarding Fed sponsored R&D
   - Reference to Microfiche Appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
3. ☒ Drawing(s)*(35 USC 113)* [Total Sheets2]
4. Oath or Declaration
   a. ☐ Newly executed (original or copy)
   b. ☒ Unexecuted original
   c. ☐ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional check boxes 5 and 16)*
      i. ☐ Deletion of Inventor(s)
      Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation by Reference *(useable if Box 4c is checked)*
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4c, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ☐ Microfiche Computer Program (Appendix)
7. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
   a. ☐ Computer Readable Copy
   b. ☐ Paper Copy (identical to computer copy)
   c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. ☐ Assignment Papers (cover sheet & document(s))
9. ☐ 37 CFR 3.73(b) Statement *(when there is an assignee)* ☐ Power of Attorney
10. ☐ English Translation Document *(if applicable)*
11. ☒ Information Disclosure Statement (IDS)/PTO-1449 ☒ Copies of IDS Citations
12. ☒ Preliminary Remarks
13. ☒ Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
14. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
15. ☐ Other:

16. ☒ If a CONTINUING APPLICATION, *check appropriate box and supply the requisite information:*
Amend the specification by inserting before the first line: -- This is a ☐ Continuation ☐ Divisional ☒ Continuation-in-Part (CIP) of prior application No.: 09/449,124, filed Nov. 24, 1999. --

17. For this divisional application, please cancel original Claims of the prior application before calculating the filing fee.

18. CORRESPONDENCE ADDRESS

☐ Customer Number or Bar Code Label or ☒ Correspondence Address below

Name: Philip S. Johnson, Esq.
Address: Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003 USA

19. TELEPHONE CONTACT

Please direct all telephone calls or telefaxes to Michele G. Mangini at:
Telephone: (732) 524-2810 Fax: (732) 524-2808

19. *SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED*

NAME	Michele G. Mangini	Reg. No. 36806
SIGNATURE	[signature]	
DATE	November 9, 2000	

FEE TRANSMITTAL	Complete if Known	
	Application Number	N/A; CIP to 09/449,124
	Filing Date	November 9, 2000
	First Named Inventor	Codispoti
	Group Art Unit	1614
	Examiner Name	
	Attorney Docket Number	MCP-264

FEE CALCULATION

CLAIMS AS FILED

(1)	(2)	(3)	(4)	(5)
FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE $710.00
TOTAL CLAIMS	26 - 20 =	6	x 18.00	$ 108.00
INDEPENDENT CLAIMS	4 - 3 =	1	x 80.00	$ 80.00
MULTIPLE DEPENDENT CLAIMS	☐	N/A	$270.00	
			TOTAL FEES	$ 898.00

METHOD OF PAYMENT

☒ Please charge Deposit Account No. 10-0750/MCP-264/MGM in the amount of $898.00. Three copies of this sheet are enclosed.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required in connection with the filing of this communication, or credit any overpayment, to Account No. 10-0750/MCP-264/MGM. Three copies of this sheet are enclosed.

SUBMITTED BY:			*Complete (if applicable)*
Typed or Printed Name	Michele G. Mangini		Reg. No. 36,806
Signature		Date: 11/9/00	**Deposit Account No. 10-0750/MCP-264/MGM**

DOCKET NO. MCP-264

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Applicant: Codispoti

For : Method For Treating Migraine Symptoms With Ibuprofen and Salts Thereof

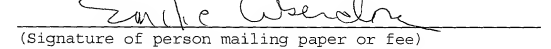
Express Mail Certificate

"Express Mail" mailing number: EL190925968US

Date of Deposit: November 9, 2000

I hereby certify that this complete Continuation in Part Application (CIP), including 9 pages of specifications with 26claims and 2 pages of 2 formal drawings, Information Disclosure Statement and Form 1449 (with 1 copy of 3 references attached), Preliminary Remarks (1pp), Utility Patent Application Transmittal (2 pps), and Declaration and Power of Attorney (unexecuted) (3pps), is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Emilie Liberatore
(Typed or printed name of person mailing paper or fee)



(Signature of person mailing paper or fee)

Docket No. MCP 264
{divisional of MCP 243}

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Codispoti	
Serial No.	:	N/A; continuation-in-part To U.S.S.N. 09/449124	Art Unit: 1614
Filed	:	November 9, 2000	Examiner: N/A
For	:	METHOD FOR TREATING MIGRAINE SYMPTOMS WITH IBUPROFEN AND SALTS THEREOF	

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY REMARKS

Dear Sir:

REMARKS

These preliminary remarks are filed concurrently with the above-referenced continuation-in-part application. The parent application, United States Application Serial No. 09/449,124 filed on 24 November 1999, received a Notice of Allowance on 19 September 2000.

Applicants also claim the benefit under Title 35, United States Code §120 of U.S. Application No. 09/449,124 filed on 24 November 1999.

This continuation in part application is filed simultaneously with an information disclosure statement attached herewith.

It is submitted that the foregoing remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

Respectfully submitted,

By: _____
Michele G. Mangini
(Attorney for Applicants)
Reg. No. 36,806
Dated: 9 Nov 2000

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2810

MCP264cipPre.amt

MCP 264
{CIP to MCP 243}

METHOD FOR TREATING MIGRAINE SYMPTOMS WITH IBUPROFEN AND SALTS THEREOF

Cross-Reference To Related Application

This Application is a continuation-in-part application of United States Application Number 09/449,124 filed on 24 November 1999, which is incorporated herein by reference in its entirety.

Field of the Invention

The present invention relates to the treatment of migraine symptoms by the administration of an effective amount of ibuprofen, more specifically the present invention relates to the treatment of phonophobia and photophobia with ibuprofen.

Background of the Invention

Migraine provides a wide variation of pain and symptoms, and associated disorders with those who suffer from the disease. Included among these symptoms are nausea, headache, moderate to severe pain, as well as incapacitating pain and total disability in a percentage of patients. Some patients also recite more specific symptoms such as photophobia, painful sensitivity to light; or phonophobia, painful sensitivity to sound.

Treatment of migraine pain includes both prescription and non-prescription or over-the-counter medication. Among the over-counter medication that is currently available is a combination of acetaminophen/aspirin/caffeine, as set forth in US Patent 5,972,916, the contents hereby incorporated by reference as set forth herein in its entirety. The combination of active ingredients suffers from the drawback that some of the actives might cause undesired side effects. For example, it is well know that aspirin can cause stomach irritation and caffeine can cause anxiety and sleeplessness.

Therefore there is a continuing need for treatment of migraine, as well as treatment alternatives to specific migraine symptoms.

Summary of the Invention

The present invention provides a method for treating photophobia and phonophobia associated with a migraine attack by providing an effective amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof. The present invention relies on the action of a single active ingredient, i.e., ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof. The present invention also contemplates the use of additional ingredients, such as flavors, binders and excipients.

Description of the Drawings

Figure 1 depicts the percentage of subjects with reduced photophobia over time after treatment with ibuprofen.

Figure 2 depicts the percentage of subjects with reduced phonophobia over time over time after treatment with ibuprofen.

Detailed Description of the Invention

Ibuprofen is a well known analgesic material that has analgesic and antipyrritic properties. It is commercially available in various forms for many years.

According to the present invention, ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, are preferably administered as an oral dose, as an effective dose to alleviate the photophobia and phonophobia symptoms, which comprises from about 100 to about 800 milligrams of ibuprofen per dose; preferably from 200 to about 600 and most preferably from about 300 to about 400 milligrams of ibuprofen per dose. Typical doses of the pharmaceutically acceptable salts of ibuprofen will vary according to the molecular weight of the salt required to give the equivalent dose of ibuprofen. Typical oral doses of pharmaceutically acceptable salts of ibuprofen range from about 110 to about 1700 milligrams per dose. Typical doeses of mixtures of ibuprofen or its isomers with pharmaceutically acceptable salts thereof range from about 100 to about 1700 milligrams per dose, preferably from about 200 to about 1300 milligrams per dose, and most preferably from about 300 to about 850 milligrams per dose. Typically doses are taken

every four to six hours, but care should be taken to avoid exceeding the daily maximum recommended dosage of ibuprofen of 2400 milligrams per day.

Examples of suitable pharmaceutically acceptable salts of ibuprofen include any of the inorganic cation salts such as sodium, potassium, lithium, magnesium, calcium, cesium, ammonia, ferrous, zinc, manganous, aluminum, ferric, and manganic; organic salts of ibuprofen with primary, secondary, tertiary and quaternary amines, or mixtures thereof. Examples of such primary, secondary, tertiary and quaternary amines include substituted amines including but not limited to naturally occurring substituted amines, cyclic amines, basic ion exchange resins, and mixtures thereof. More specifically, suitable amines include but are not limited to triethylamine, tripropylamine, 2-dimethylaminoethanol, 2-diethylaminoethanol, lysine, arginine, histidine, caffeine, procain, N-ethylpiperidine, hydrabamine, choline, betaine, ethylenediamine, glucosamine, TRIS(hydroxymethyl)-aminomethane, methylglycamine, theobromine, pruines, piperazine, piperidine, polyamine resins and the like, and mixtures thereof. In one embodiment, a mixture of ibuprofen and its sodium salt may be used.

Examples of suitable isomers include, but are not limited to R-ibuprofen, S-ibuprofen and mixtures thereof.

Suitable dosage forms include solids or liquids. Solid forms include tablets, capsules, liquid-filled soft gelatin capsules, powders, sachets and the like. Suitable liquids include suspensions, solutions, emulsions and the like.

The ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, may be admixed with various pharmaceutically-acceptable excipients and other ingredients including but not limited to diluents, granulating agents, disintegrating agents, binding agents, lubricants and the like. Examples of these various ingredients are set forth in US Patent 5,660,860, the contents hereby incorporated by reference as if set forth in its entirety.

The present invention as set forth in the following examples are meant to exemplify the various aspects of carrying out the present invention and are not intended to limit the invention in any way.

Example 1

Subjects suffering from photophobia due to a migraine were either given a placebo or treated with 200 or 400 milligrams of ibuprofen. Approximately 650 subjects were in the study. Some subjects were given placebos, while others were given either 200 or 400 milligrams of ibuprofen. Periodic assessments of their photophobia were made and the results are presented in Figure 1. The results indicate that at time of two hours or longer the treatment of photophobia with ibuprofen was effective in relieving photophobia

Example 2

Subjects suffering from phonophobia due to a migraine were either given a placebo or treated with 200 or 400 milligrams of ibuprofen in tablet form. Periodic assessments of their photophobia were made and the results are presented in Figure 2. The results indicate that at time of two hours or longer the treatment of photophobia with ibuprofen was effective in relieving photophobia.

I claim:

1. A method for mitigating or treating photophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, as the sole pharmaceutically effective ingredients.

2. The method of claim 1 wherein the amount of ibuprofen, isomers thereof, or mixtures thereof, is from about 100 to about 800 milligrams per dosage.

3. The method of claim 1 wherein the amount of ibuprofen, isomers thereof, or mixtures thereof, is from about 200 to about 600 milligrams per dose.

4. A method for mitigating or treating phonophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, as the sole pharmaceutically active ingredients.

5. The method of claim 4 wherein the amount of ibuprofen, isomers thereof, or mixtures thereof, is from about 100 to about 800 milligrams per dosage.

6. The method of claim 4 wherein the amount of ibuprofen, isomers thereof, or mixtures thereof, is from about 200 to about 600 milligrams per dose.

7. The method of claim 1 wherein the amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, is about 200 milligrams per dose.

8. The method of claim 1 wherein the amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, is about 400 milligrams per dose.

9. The method of claim 4 wherein the amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, is about 200 milligrams per dose.

10. The method of claim 4 wherein the amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, is about 400 milligrams per dose.

11. The method of claim 1 wherein the pharmaceutically acceptable salts of ibuprofen are selected from the group consisting of:

a) inorganic cation salts;

b) organic salts of ibuprofen with pharmaceutically acceptable primary, secondary, tertiary, and quaternary amines; and

c) mixtures thereof.

12. The method of claim 1 wherein the pharmaceutically acceptable salt of ibuprofen is :

a) an inorganic cation salt selected from sodium, potassium, lithium, magnesium, calcium, cesium, ammonia, ferrous, zinc, manganous, aluminum, ferric, and manganic;

b) an organic salt of ibuprofen with primary, secondary, tertiary and quaternary amines selected from triethylamine, tripropylamine, 2-dimethylaminoethanol, 2-diethylaminoethanol, lysine, arginine, histidine, caffeine, procain, N-ethylpiperidine, hydrabamine, choline, betaine, ethylenediamine, glucosamine, TRIS(hydroxymethyl)aminomethane, methylglycamine, theobromine, pruines, piperazine, piperidine, and polyamine resins; or

c) mixtures thereof.

13. The method of claim 1 wherein the mixture is a mixture of ibuprofen and its potassium salt.

14. The method of claim 1 wherein the isomer of ibuprofen is selected from the group consisting of R-ibuprofen, S-ibuprofen and mixtures thereof.

15. The method of claim 4 wherein the pharmaceutically acceptable salts of ibuprofen are selected from the group consisting of:

a) inorganic cation salts;

b) organic salts of ibuprofen with pharmaceutically acceptable primary, secondary, tertiary, and quaternary amines; and

c) mixtures thereof.

16. The method of claim 4 wherein the pharmaceutically acceptable salt of ibuprofen is :

a) an inorganic cation salt selected from sodium, potassium, lithium, magnesium, calcium, cesium, ammonia, ferrous, zinc, manganous, aluminum, ferric, and manganic;

b) an organic salt of ibuprofen with primary, secondary, tertiary and quaternary amines selected from triethylamine, tripropylamine, 2-dimethylaminoethanol, 2-diethylaminoethanol, lysine, arginine, histidine, caffeine, procain, N-ethylpiperidine, hydrabamine, choline, betaine, ethylenediamine, glucosamine, TRIS(hydroxymethyl)aminomethane, methylglycamine, theobromine, pruines, piperazine, piperidine, and polyamine resins; or

c) mixtures thereof.

17. The method of claim 4 wherein the mixture is a mixture of ibuprofen and its potassium salt.

18. The method of claim 4 wherein the isomer of ibuprofen is selected from the group consisting of R-ibuprofen, S-ibuprofen and mixtures thereof.

19. The method of claim 1 wherein the amount of the pharmaceutically acceptable salts of ibuprofen is from about 100 to about 1700 milligrams per dose.

20. The method of claim 4 wherein the amount of the pharmaceutically acceptable salts of ibuprofen is from about 100 to about 1700 milligrams per dose.

21. The method of claim 1 wherein the amount of the mixtures of ibuprofen, isomeres thereof, and pharmaceutically acceptable salts thereof is from about 100 to about 1700 milligrams per dose.

22. The method of claim 1 wherein the amount of the mixtures of ibuprofen, isomeres thereof, and pharmaceutically acceptable salts thereof is from about 200 to about 1300 milligrams per dose.

23. The method of claim 4 wherein the amount of the mixtures of ibuprofen, isomers thereof, and pharmaceutically acceptable salts thereof is from about 100 to about 1700 milligrams per dose.

24. The method of claim 4 wherein the amount of the mixtures of ibuprofen, isomers thereof, and pharmaceutically acceptable salts thereof is from about 200 to about 1300 milligrams per dose.

25. A method for mitigating or treating photophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen as the sole pharmaceutically effective ingredient.

26. A method for mitigating or treating phonophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen as the sole pharmaceutically active ingredient.

ABSTRACT OF THE INVENTION

The present invention provides a method for treating the photophobia and phonophobia symptoms of migraine attacks with an effective amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof.

FIG. 1

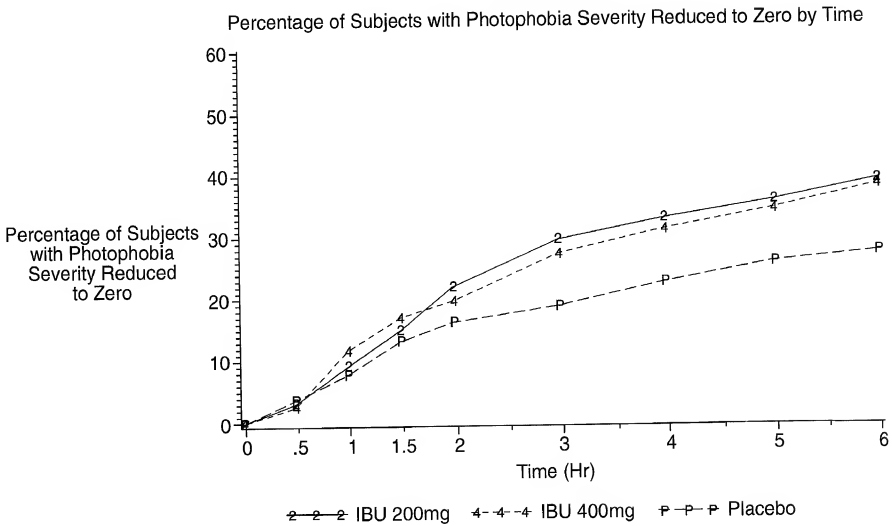
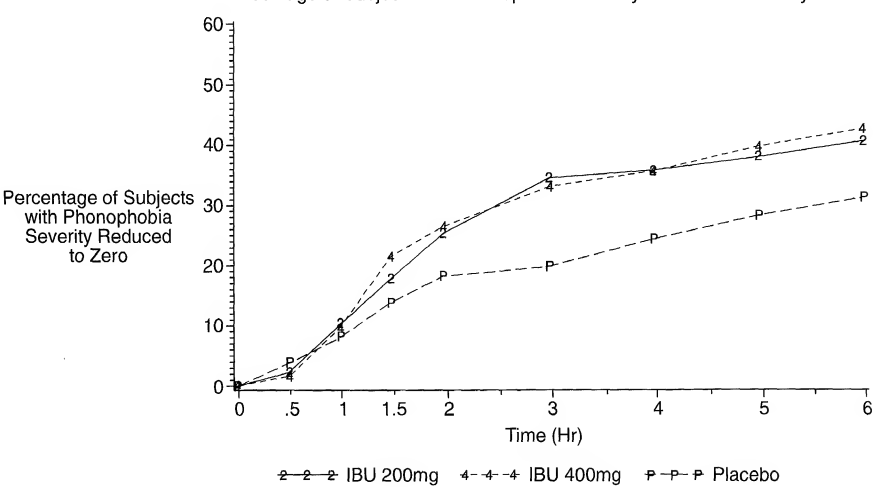


FIG. 2



DOCKET NO. MCP-264

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled Method For Treating Migraine Symptoms With Ibuprofen and Salts Thereof, the specification of which

(check one) ☐ is attached hereto.

☐ was filed on _____ as

Application Serial No. _____

and was amended on _____.
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 (a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(Application Number) (Filing Date)

(Application Number) (Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status
09/449,124	November 24, 1999	Pending

Application Serial No.	Filing Date	Status

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Steven P. Berman (Reg. #24,772), Andrea L. Colby (Reg. #30,194), Paul A. Coletti (Reg. #32,019), Matthew S. Goodwin (Reg. #32,839), Ralph R. Palo (Reg. #29,486), Bernard F. Plantz (Reg. #32,091), Joseph F. Shirtz (Reg. #31,880), Michael Stark (Reg.

#32,495), Mark R. Warfield (Reg. #33,463), and Michele G. Mangini (Reg. #36,806) One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

Address all telephone calls to Michele G. Mangini at telephone no. (732) 524-2810.

Address all correspondence to Philip S. Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Inventor's Signature: _____

Full Name of Sole or First Inventor: Joseph R. Codispoti

Date: _____

Citizenship: USA

Residence: 13001 Worthington Road, Philadelphia, PA 19116

Mailing Address: Same as above